

REMARKS

Claim 6 has been revised to better tailor the language to subject matter of interest. The revision is not made for any reason related to patentability, because claim 6 was withdrawn from consideration and so has not been examined.

Claims 7 and 9 have been revised to utilize “consisting of” as the transition phrase without prejudice for re-presentation of the previously presented subject matter in a continuing application. These claims have also been revised to use alternate language to encompass the *Notoginseng radix* extract without acquiescence to any rejection of record. No change in claim scope is intended or believed to have occurred with the use of the alternative language.

No new matter has been introduced, and entry of the above revised claims is respectfully requested.

Restriction Requirement and Withdrawal of Claims 6 and 12

Claims 6 and 12 were withdrawn from consideration as allegedly directed to patentably distinct subject matter. Applicants respectfully point out that method claims 6 and 12 contain all the features present in examined claim 7 and so are subject to rejoinder with claim 7 under the standard set forth at MPEP 821.04 and 821.04(b) and the case decisions cited therein.

Confirmation of Applicants’ understanding in the next Office Communication is respectfully requested.

Alleged Rejection under 35 U.S.C. § 112, Second Paragraph

Claims 7-11 have been rejected under 35 U.S.C. §112, second paragraph as allegedly indefinite. The basis for this rejection is unclear, and so Applicants respectfully traverse because no *prima facie* case of indefiniteness has been presented.

Alleged Rejections under 35 U.S.C. § 102

Claims 7-11 have been rejected under 35 U.S.C. §102(b) as allegedly anticipated by Lin et al. (CN 14188690A). Applicants have carefully reviewed the statement of the rejection and respectfully traverse because no *prima facie* case of anticipation is possible against the claims presented above. Reconsideration and withdrawal thereof are respectfully requested.

The instant rejection is based upon the assertion that “the claims herein use the open transitional phrase and does not exclude all else in the ethanol extract, the butanol fraction is considered part of the ethanol extract composition.” But the claims as revised above now utilize “consisting of” as the transitional phrase. Therefore, Applicants respectfully submit that the claimed subject matter does not encompass the residual part of the ethanol extract (as reported by Lin et al.) aside from the butanol fraction.

Therefore, there is no identity between the claimed subject matter and the Lin et al. document. Accordingly, no *prima facie* case of anticipation is present, and this rejection may be properly withdrawn.

Claims 7-11 have been rejected under 35 U.S.C. §102(b) as allegedly anticipated by Cui et al. (CN 1348796A). Applicants have carefully reviewed the statement of the rejection and respectfully traverse because no *prima facie* case of anticipation is possible against the claims presented above. Reconsideration and withdrawal thereof are respectfully requested.

The instant rejection is based upon the assertion that the claims “do[] not exclude all else in the ethanol extract” reported by Cui et al. But the claims as revised above now utilize “consisting of” as the transitional phrase. Therefore, Applicants respectfully submit that the claimed subject matter does not encompass an ethanol extract as reported by Cui et al. but are instead directed to a butanol fraction.

Therefore, there is no identity between the claimed subject matter and the Cui et al. document. Accordingly, no *prima facie* case of anticipation is present, and this rejection may be properly withdrawn.

Claims 7-11 have been rejected under 35 U.S.C. §102(b) as allegedly anticipated by Liu et al. (U.S. Patent No. 4,755,504). Applicants have carefully reviewed the statement of the rejection and respectfully traverse because no *prima facie* case of anticipation is possible against the claims presented above. Reconsideration and withdrawal thereof are respectfully requested.

The instant rejection is based upon the assertion that the claims “use the open transitional phrase and do[] not exclude all else in the ethanol extract” of Liu et al. But the claims as revised above now utilize “consisting of” as the transitional phrase. Therefore,

Applicants respectfully submit that the claimed subject matter does not encompass an ethanol extract as reported by Liu et al. but are instead directed to a butanol fraction.

Therefore, there is no identity between the claimed subject matter and the Liu et al. document. Accordingly, no *prima facie* case of anticipation is present, and this rejection may be properly withdrawn.

Additional Comments Related to the Documents Cited Under 35 U.S.C. § 102

Lin et al. and Cui et al.

Applicants respectfully point out that the claimed subject matter is based in part on the discovery that the butanol fraction as featured in the claimed compositions and methods is effective in treating arthritis. This discovery is not disclosed or suggested in any of the cited documents, whether taken individually or in any combination.

For example, Lin et al. only reports that an ethanol extract of *Notoginseng radix* is effective in preventing and treating angiocardopathy and cerebrovascular diseases. On the other hand, Cui et al. reports that a medical composition comprising the ethanol extract of seven plants and boneol has pain curing effects.

So with respect to the effectiveness of the featured butanol fraction of *Notoginseng radix* in treating arthritis, Lin et al. and Cui et al. do not disclose or suggest anything relevant thereto.

Comparative results

The butanol fraction as featured in the claimed compositions and methods has superior effects in treating arthritis as compared to an ethanol extract.

Applicants enclose herewith a Declaration by co-inventor Jung-Keun Kim under 37 C.F.R. § 1.132 which demonstrates the butanol fraction as having superior effects in i) inhibiting the progression of arthritis, and ii) cell toxicity, as compared to an ethanol extract. This Declaration is believed to be of greater relevance to claims 6 and 12, upon their rejoinder with examined claims 7-11. Because claims 6 and 12 were only held as withdrawn from consideration in the Office Action mailed July 13, 2007, this Declaration could not have been previously presented.

Liu et al.

As for Liu et al., their report regarding a mixed composition (named “ACT”) of saponin and quercetin in relation to anti-inflammation is distinct from the claimed subject matter. Simply put, anti-inflammation effects and arthritis treatment are distinct from each other.

For example, the animal test models for the two are different. The animal test model reported by Liu et al. to demonstrate an anti-inflammatory effect is different from the animal test model used generally to evaluate a test agent’s effect on arthritis. The inflammation from arthritis is chronic inflammation characterized by flare, bloat, and ache. In particular, rheumatoid arthritis falls within the categories of systemic and chronic inflammatory disease. Therefore, a chronic inflammatory animal test model is used to evaluate the effect for the inflammation component in arthritis. In the Type 2 collagen-induced arthritis (CIA) chronic inflammation animal test model, which is systemic inflammation models, the effects on the inhibition of arthritis progression are evaluated by the method of measuring the arthritis index for about 15 to 21 days.

This is distinct from the anti-inflammation animal test model, which is experimental in nature, where inflammation is induced by inducing cells to come together by creating an air-pouch and then injecting croton oil into the air-pouch. This model is for subacute inflammation, not for chronic inflammation, and is not a general test model currently used to evaluate the effects of a test agent on arthritis. Instead, this test model, where inflammation is induced by transient inflammatory reaction in an air-pouch, is useful for research on the influence of subacute inflammation on other organs, angiogenesis, wound healing mechanisms, and recruiting leukocytes. Additionally, the symptoms observed in this animal test model are totally different from the flare, bloat and ache observed in the inflammation of arthritis, especially the systemic inflammation symptoms observed in rheumatoid arthritis.

Therefore, Liu et al. report an ethanol extract, which is distinct from the claimed subject matter featuring a butanol extract, as well as use of the ethanol extract in an animal model system that is inapplicable with respect to use of the butanol extract in the treatment of arthritis. Accordingly, Liu et al. provide no basis to anticipate, or otherwise render unpatentable, the claimed invention.

Conclusion

It is believed that the application is now in condition for allowance. Applicant requests the Examiner to issue a notice of Allowance in due course. The Examiner is encouraged to contact the undersigned to further the prosecution of the present invention.

The Commissioner is authorized to charge JHK Law's Deposit Account No. 502486 for any fees required under 37 CFR §§1.16 and 1.17 that are not covered, in whole or in part, by a credit card payment enclosed herewith and to credit any overpayment to said Deposit Account No. 502486.

Respectfully submitted,

JHK Law

Dated: October 16, 2007

By: /Joseph Hyosuk Kim/
Joseph Hyosuk Kim, Ph.D.
Reg. No. 41,425

P.O. Box 1078
La Canada, CA 91012-1078
(818)249-8177 – direct; (818)249-8277 – fax